

# NCI Deputy Director's Update

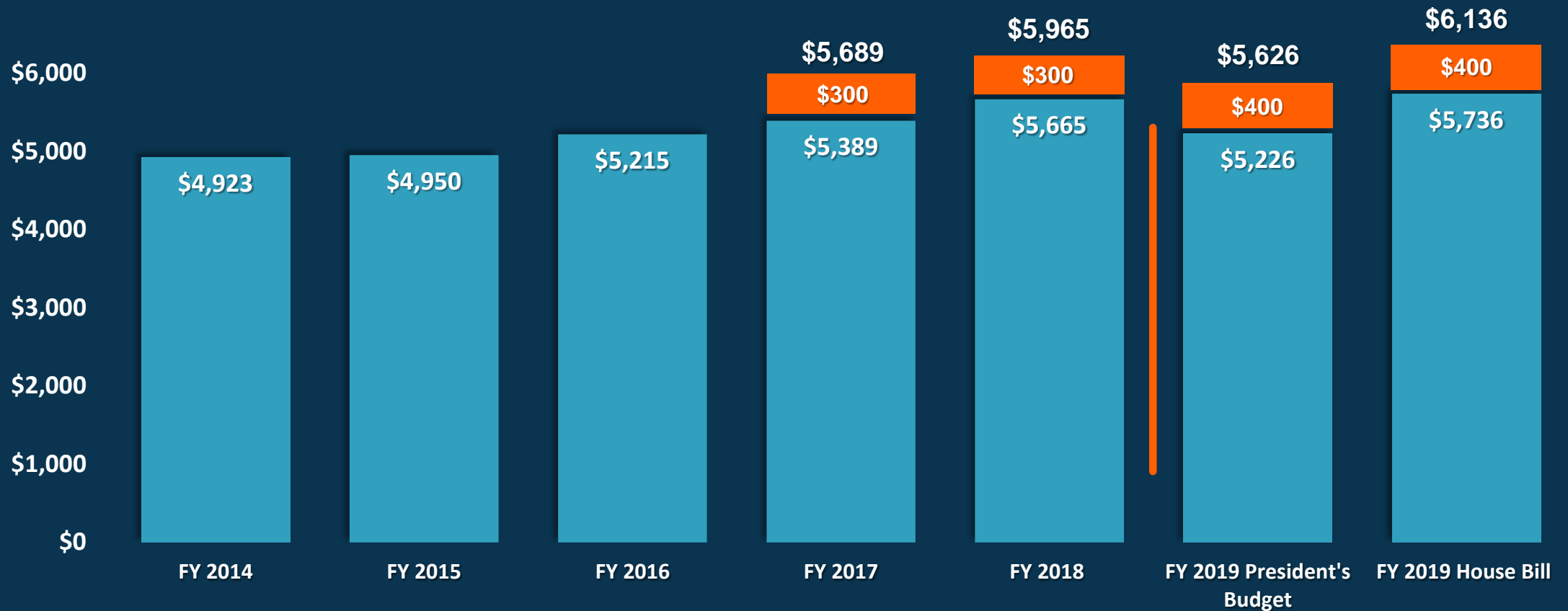
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James H. Doroshow, M.D.

July 11, 2018

# NCI Appropriations FY 2014-2019

(in millions)



Source: NCI Office of Budget and Finance

# FY 2018 NCI Budget Overview

(dollars in thousands)

Appropriation Increase over FY 2017 <sup>1</sup>	
FY 2017 Enacted	\$5,389,329
FY 2018 Enacted	\$5,664,800
<b>Appropriation Increase</b>	<b>\$275,471</b>

<sup>1</sup> Does not include \$300M 21st Century Cures funding for Cancer Moonshot

Estimated Increase, as of 6/22/2018	
Taps, Assessments, Transfers, Salaries & Benefits	\$37,900
Small Business Set Aside	\$10,000
Additional Investments in the RPG Pool	\$147,000
Centers and SPOREs	\$20,000
Targeted Research Opportunities	\$50,571
NCTN and NCORP	\$10,000
<b>Total</b>	<b>\$275,471</b>



# FY 2018 NCI Budget Overview

## Targeted Research Opportunities<sup>1</sup>

Genomic Profiling of Lung Cancer in Never Smokers in General & Special Populations

### **The Cancer Imaging Archive**

Data Integration and Analysis for APOLLO

### **Glioblastoma Research Pilot Project**

New Onset Diabetes (NOD) Cohort Biorepository

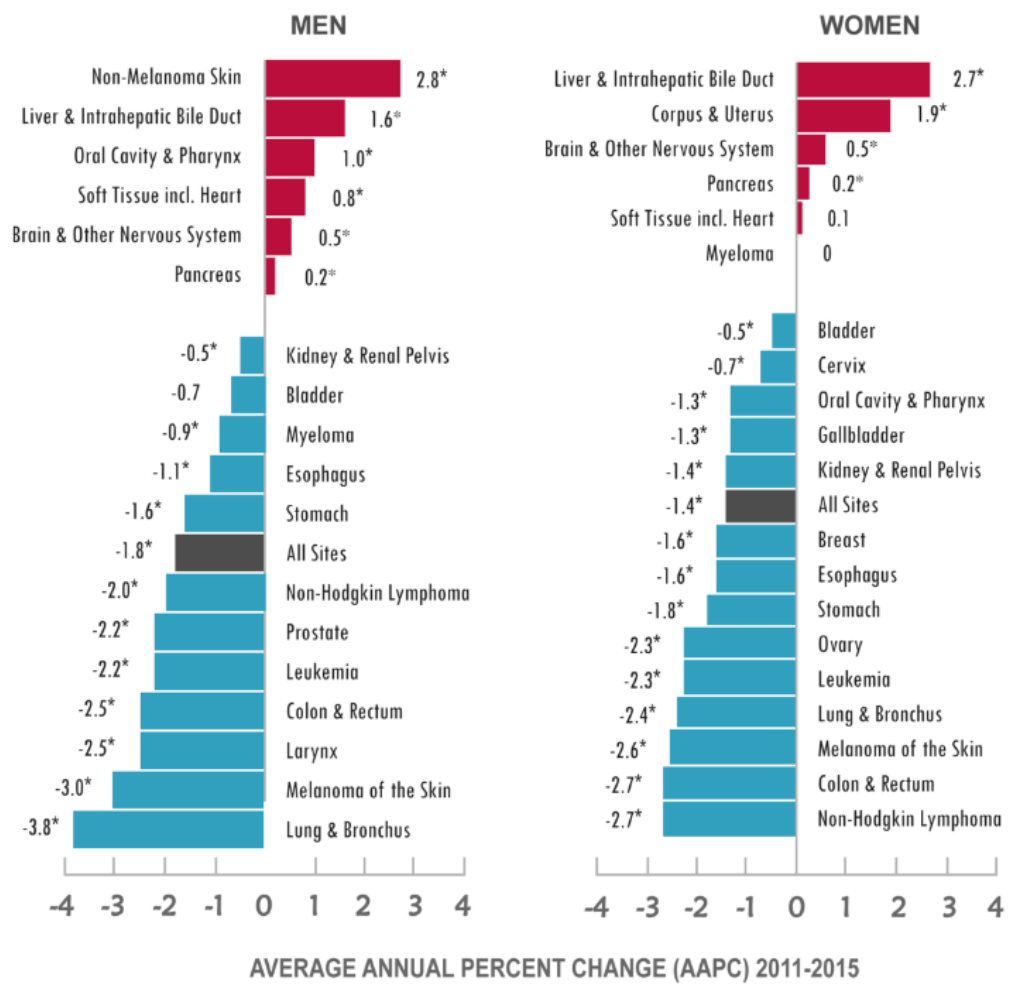
Cancer Research Education Grants to Promote Diversity (R25's)

*<sup>1</sup> This table does not represent the entire population of Targeted Research Opportunities in FY 2018, but rather a select few*

# ANNUAL REPORT TO THE NATION ON THE STATUS OF CANCER

1999 — 2015  
**CANCER  
DEATH RATES  
DECLINED**  
FOR MEN, WOMEN, & CHILDREN

## NATIONAL TRENDS IN CANCER DEATH RATES



# Cancer Moonshot

Sept. 2016

Blue Ribbon Panel  
Recommendations



Dec. 2016



21<sup>st</sup> Century Cures Act  
Authorized Funding for  
Cancer Moonshot

Apr.-Jun. 2017

NCI Teams, Leaders & BSA Develop  
& Review Scientific Proposals Aligned  
with BRP Recommendations



Fall 2017



\$300M Awarded  
FY2018 FOAs Released

# Recently Approved Concepts

<b>CONCEPT</b>	<b>DOC</b>
<b>Implementation Science Centers for Cancer Control</b>	<b>DCCPS</b>
<b>Communication and Decision Making in the Context of Risk and Uncertainty for Individuals with Inherited Cancer Syndromes</b>	<b>DCCPS</b>
<b>Moonshot New RFAs - Immuno-Oncology Translational Network</b>	<b>DCB</b>
<b>NCI Awardee Skills Development Consortium (NASDC)</b>	<b>OD-CCT</b>
<b>Pathway to Independence Award for Outstanding Early-Stage Postdoctoral Fellows (RFA: K88/R00)</b>	<b>OD-CCT</b>
<b>U.S.-China Program for Biomedical Collaborative Research</b>	<b>OD-CGCHR, DCB, DCCPS, DCP, DCTD</b>
<b>The Experimental Therapeutics Clinical Trials Network (previous title Early Clinical Trials of New Anticancer Agents With Phase 1 and 2 Emphasis)</b>	<b>DCTD</b>

# Key Focus Areas

## **BASIC SCIENCE**

Reaffirm our commitment to basic science to drive novel approaches and technologies

## **WORKFORCE DEVELOPMENT**

Support the cancer research enterprise by focusing on the workforce of cancer investigators

## **BIG DATA**

Increase data aggregation and interpretation to speed our work across the cancer enterprise

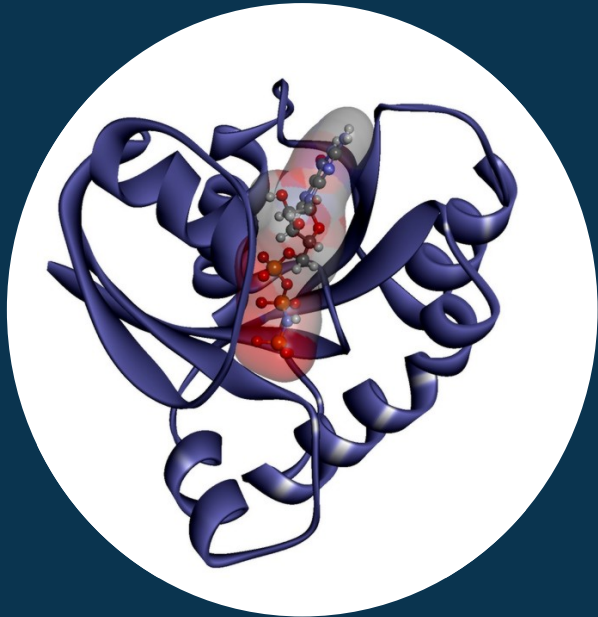
## **CLINICAL TRIALS**

Fully realize the power of clinical trials through innovative design, administration, and analyses





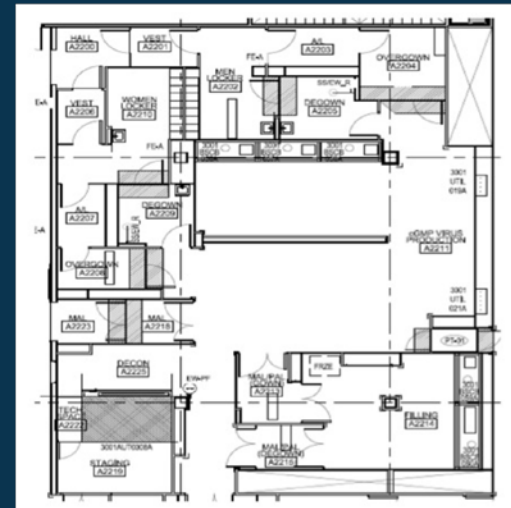
# Basic Science: Frederick National Lab Updates



**RAS**



**CryoEM**



**Frederick Cell Facility**

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# Early Stage Investigators



**Method to Extend  
Research in Time  
R37 Award**

**NCI recognizes that Early Stage Investigators (ESI) face challenges.**

**In addition to increased ESI payline, NCI is announcing its new use of the MERIT Award in 2018.**

**The award gives eligible investigators applying for first R01 the opportunity to obtain up to seven years of grant funding (5+2)**

**This will provide critical time for ESIs to launch their careers and become more established before attempting renewal.**

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# Big Data: Data Infrastructure Investments

- Cancer Cloud Resources
- Data Commons Framework Services
- New reporting tools for better insight into active clinical trials
- Recommitment to DOE collaboration\*
- Prototype CRDC nodes for imaging and proteomics\*
- Collaborations that enable integration of EHR and insurance claims data with SEER\*

\*Supported by funds authorized by the 21<sup>st</sup> Century CURES Act.

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# Clinical Trials

**NATIONAL CANCER INSTITUTE  
NCI-MATCH CLINICAL TRIAL**

THIS PRECISION MEDICINE TRIAL EXPLORES TREATING PATIENTS BASED ON THE MOLECULAR PROFILES OF THEIR TUMORS

NCI-MATCH\* IS FOR ADULTS WITH:

- solid tumors (including rare tumors) and lymphomas
- tumors that no longer respond to standard treatment

ABOUT 5,000 CANCER PATIENTS WILL BE SCREENED FOR TUMOR

THE BIOPSY TUMOR

**MATCH**

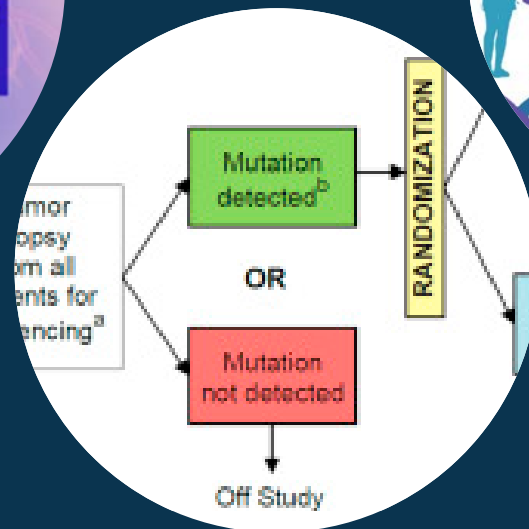
Trial Metrics: S1400	
Metric	Value
Total sites open for S1400	628
Total pts registered to S1400	1672
Total pts registered to S1400A	116
Total pts registered to S1400B	39
Total pts registered to S1400C	53
Total pts registered to S1400D	43
Total pts registered to S1400E	9
Total pts registered to S1400G	48
Total pts registered to S1400I	275

**LungMAP**

**ALCHEMIST  
PRECISION MEDICINE TRIAL**

for patients with early-stage non-small cell lung cancer

**ALCHEMIST**



**NCI-MPACT**

**NATIONAL CANCER INSTITUTE  
NCI-Children's Oncology Group Pediatric MATCH Trial\***

Precision medicine clinical trial, funded by NCI and conducted by COG, matches children and adolescents with treatment based on genetic changes in their tumors.

**Pediatric MATCH is for patients ages 1 to 21 who have both:**

- Solid tumors, including lymphomas and brain tumors, or histiocytoses
- Tumors that no longer respond to standard treatment or that have come back after treatment

ABOUT 200-300 PEDIATRIC PATIENTS ARE EXPECTED TO BE SCREENED EACH YEAR

UNDERGO TESTING FOR CHANGES IN MORE THAN 140 GENES

patient's tumor has a specific

**Pediatric MATCH**

# Trial Assigning Individualized Options for Treatment (TAILORx)



*“Results from TAILORx give clinicians high-quality data to inform personalized treatment recommendations for women”*

- Joseph A. Sparano, MD

- **21-gene recurrence-score assay** (Oncotype DX, Genomic Health) predicts breast cancer recurrence
- Women with early-stage, HR-positive, HER2-negative, axillary lymph node-negative breast cancer and **INTERMEDIATE score were randomly assigned** to receive hormone therapy alone or hormone therapy with adjuvant chemotherapy
- **No benefit from receiving chemotherapy** plus hormone therapy versus hormone therapy only for most intermediate-risk women (except some  $\leq 50$  years old)





# NAVIGATE

**NCI and VA Interagency Group  
to Accelerate Trials Enrollment**

NAVIGATE will make it easier for veterans to access state-of-the-art treatments via clinical trials by bringing NCI trials to them, rather than seeking treatment outside of the Veterans Health Administration.



**VA**



**U.S. Department of Veterans Affairs**  
Veterans Health Administration

# NAVIGATE Goals

- Enable more VA patients to enroll in NCI national clinical trials
- Provide infrastructure funding support to 12 VA sites for enrollment of VA patients to NCTN and NCORP clinical trials
- Facilitate policy, operational, or other changes to promote conduct of cancer clinical trials at VA
- Longer term goals include seeking ways to sustain VA participation in NCI clinical trials

VA



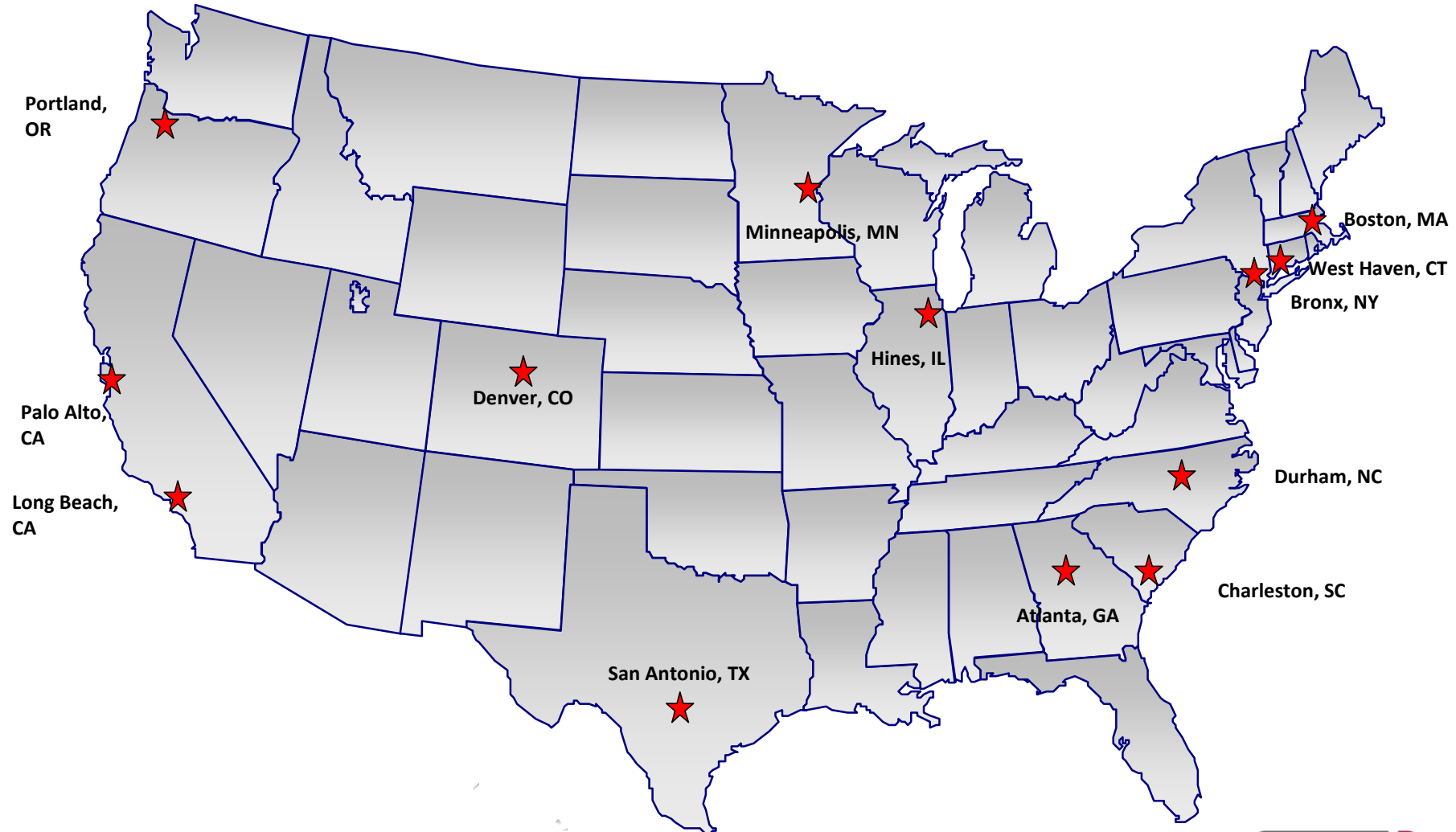
U.S. Department of Veterans Affairs

Veterans Health Administration

NIH

NATIONAL  
CANCER  
INSTITUTE

# NAVIGATE SITES



**U.S. Department of Veterans Affairs**  
Veterans Health Administration  
Office of Research & Development



**NATIONAL  
CANCER  
INSTITUTE**

# NAVIGATE NETWORK

LOCATION	PI(s)
Atlanta, GA	Wayne Harris, MD
Bronx, NY / James J. Peters VAMC	Susan Bates, MD
Charleston, SC / Ralph H. Johnson VAMC	Rinah Shopnik DO, Stephen Savage, MD
Denver, CO	Daniel Bowles, MD
Durham, NC	Daphne Friedman, MD
Edward Hines Jr (IL) VAMC	Cheryl Czerlanis, MD
Long Beach (CA) / Tibor Rubin VAMC	Viola Zhu, MD, PhD
Minneapolis, MN	Sharon Luikart, MD, Mark Klein, MD
Palo Alto, CA	Harlan Pinto, MD
Portland, OR	Mark Garzotto, MD
San Antonio, TX	Michael Liss, MD, Paromita Datta, MD
West Haven, CT	Herta Chao, MD, PhD
Boston, MA (Coordinating Center)	Mary Brophy, MD, MPH



**U.S. Department of Veterans Affairs**  
 Veterans Health Administration  
 Office of Research & Development



**NATIONAL  
 CANCER  
 INSTITUTE**

Alan Rabson, M.D.  
1926-2018



# 2018 Cancer Clinical Investigator Team Leadership Recipients

# Cancer Clinical Investigator Team Leadership Award

## Purpose:

- Recognize and support outstanding clinical investigators at NCI-designated Cancer Centers who are actively engaged in NCI-funded collaborative clinical trials.
- Promote the retention of clinical investigators in academic clinical research careers.

# Cancer Clinical Investigator Team Leadership Award

- **10 to 13 new awards per year**
- **\$60,000 per year for 2 years**
- **15% effort; time protected by sponsoring institution**
- **Candidate nominated by NCI Cancer Center Director**
- **First awards made in 2009; 114 recipients to date**
- **93% (53/57) remain at NCI-Designated Cancer Center 5 years after award**



# Cancer Clinical Investigator Team Leadership Award

## Supported activities include:

- Engaging fellows and new faculty in collaborative clinical research efforts
- Mentoring
- Organizing courses, lecture/seminar series, educational sessions, or workshops related to clinical trials
- Participating on cancer center committees related to clinical trials
- Developing a clinical trial
- Designing and implementing initiatives to better coordinate, support and integrate clinical trials efforts at the institution

# **Cancer Clinical Investigator Team Leadership Award**

## **Eligibility:**

- **Engaged in conducting NCI-funded cancer clinical trials**
- **Practicing at least 3 years but no more than 8 years post-fellowship**
- **Currently practicing in the oncology clinical setting; board certified**
- **Full-time faculty member, assistant or associate professor level**
- **Physician or oncology nurse, clinical psychologist, or similarly qualified clinician with a doctoral degree**

# 2018 Award Recipients

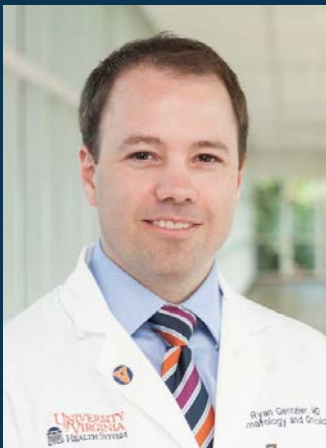
# 2018 CCITLA Recipients



**Amy DeZern, MD, MHS**

**Sidney Kimmel Comprehensive Cancer Center  
Johns Hopkins University**

**Focus: Myelodysplastic syndromes, aplastic anemia,  
leukemia**



**Ryan Gentzler, MD, MS**

**UVA Cancer Center, University of Virginia**

**Focus: Thoracic oncology, immunotherapy**

# 2018 CCITLA Recipients



**Ahmad Halwani, MD**

**Huntsman Cancer Institute, University of Utah**

**Focus: Immune therapy in lymphoid malignancies, real world practices & outcomes using electronic health records information**



**Caron Jacobson, MD, MMS**

**Dana-Farber/Harvard Cancer Center**

**Focus: Lymphoma, immunotherapy**

# 2018 CCITLA Recipients



**Michael Liss, MD, MAS**

**Cancer Therapy & Research Center  
University of Texas Health Science Center at  
San Antonio**

**Focus: Genitourinary cancers**



**Jason Luke, MD**

**University of Chicago Comprehensive Cancer  
Center**

**Focus: Melanoma, advanced solid tumors,  
immunotherapy**

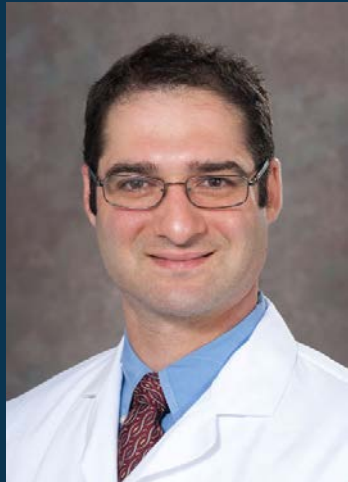
# 2018 CCITLA Recipients



**Aaron Mansfield, MD**

**Mayo Clinic Cancer Center**

**Focus: Thoracic oncology, early phase trials,  
drug development**



**Jonathan Riess, MD, MS**

**UC Davis Comprehensive Cancer Center**

**Focus: Lung cancer, immunotherapy**

# 2018 CCITLA Recipients



**Solmaz Sahebjam, MD**

**Moffitt Cancer Center**

**Focus: Neuro-oncology, early phase trials,  
drug development**



**Robert Wesolowski, MD**

**The Ohio State University Comprehensive Cancer  
Center**

**Focus: Breast cancer, early phase trials in patients  
with solid tumors, drug development**



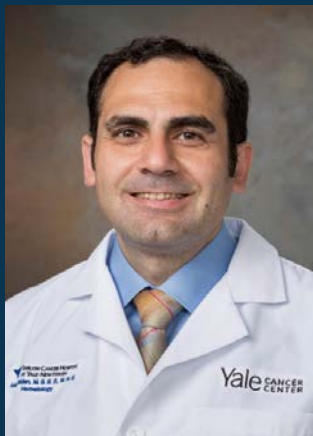
# 2018 CCITLA Recipients



**Karen Winkfield, MD, PhD**

**Wake Forest Baptist Comprehensive Cancer Center**

**Focus: Radiation therapy for the treatment of hematologic malignancies, health disparities**



**Amer Zeidan, MBBS, MHS**

**Yale Cancer Center**

**Focus: Myelodysplastic syndrome, acute myeloid leukemia, immunotherapy, effectiveness and outcomes research in hematologic malignancies**

**Congratulations!**

**Cancer Clinical Investigator Team  
Leadership Awardees**

**Thank You!**

**Reviewers**

**CCCT Program Staff**

**Jennifer Hayes**

**Sarah Fabian**



**NATIONAL  
CANCER  
INSTITUTE**

**[cancer.gov](https://cancer.gov)**

**[cancer.gov/espanol](https://cancer.gov/espanol)**